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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,026	07/06/2001	Andre Stamm	107664.115US3	7379

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,026	STAMM ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *162-238* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *162-238* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/005,128.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under Rule 1.114 and the Amendment, both filed 09/08/03 is acknowledged.

Claims 162-238 are pending. Claims 91-161 have been cancelled. Claims 162-238 are rejected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 162-238 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 6,652,881. Although the conflicting claims are not identical, they are not patentably distinct from each other because each discloses in the claims at least the following:

Fenofibrate in micronized form having a particle size of less than or equal to 20 microns (μm); a hydrophilic polymer (polyvinylpyrrolidone); a surfactant and fenofibrate comprising inert carrier particles (lactose).

The instant claims (162-238) of application no. 09/899,026 are generic in relation to species claims (1-41) of the 6,652,881 patent. Furthermore, the species embraced in the US patent 6,652,881 are embodied in the generic claims of the instant application. Therefore, the claims of US patent 6,652,881 are considered obvious.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 162-169, 171-185, 189-197, 201-211, 213-227 and 231-238 are rejected under 35 U.S.C. 102(b) as being anticipated by Curtet *et al.* (US Pat. No. 4,895,726).

Curtet *et al.* disclose a micronized fenofibrate composition containing a micronized mixture of particles of fenofibrate and a solid surfactant and method for preparing the fenofibrate composition comprising (i) intimately mixing and then co-micronizing the fenofibrate and the solid surfactant, (ii) adding lactose and starch to the mixture obtained, (iii) converting the whole to granules in the presence of water, (iv)

drying the granules until they contain no more than 1% of water, (v) grading the granules, (vi) adding polyvinylpyrrolidone and magnesium stearate to the graded granules and (vii) filling gelatin capsules with the mixture obtained in stage (vi). The mean particle size of the micronized mixture obtained is less than 15 microns (μm) (see reference column 2, lines 5-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 170, 186-188, 198-200, 212 and 228-230 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtet *et al.* (US Pat. No. 4,895,726) alone or in view of Klimesch *et al.* (US Pat. No. 5,073,379).

Curtet et al., as discussed above, teach a micronized fenofibrate composition containing a micronized mixture of particles of fenofibrate and a solid surfactant and method for preparing the fenofibrate composition comprising (i) intimately mixing and then co-micronizing the fenofibrate and the solid surfactant, (ii) adding lactose and starch to the mixture obtained, (iii) converting the whole to granules in the presence of water, (iv) drying the granules until they contain no more than 1% of water, (v) grading the granules, (vi) adding polyvinylpyrrolidone and magnesium stearate to the graded granules and (vii) filling gelatin capsules with the mixture obtained in stage (vi). The mean particle size of the micronized mixture obtained is less than 15 microns (μm) (see reference column 2, lines 5-20).

Curtet teaches that the surfactant used is an alkali metal sulfate of lauryl alcohol, for example, sodium lauryl-sulfate. The recommended amount of sodium lauryl-sulfate will be between 0.5% and 7% by weight. The weight ratio of the surfactant/fenofibrate will be between about 0.75/100 and 10.5/100 (col. 1, lines 52-60). The co-micronization of the fenofibrate and the solid surfactant will advantageously be carried out in an accelerated air-jet mill until the powder obtained is such that the mean particle size is less than 15 microns, preferably less than 10 (μm) and particularly preferably less than 5 (μm) (col. 1, lines 61-66).

Conventional filling, dispersing and flow-enhancing excipients, for example lactose, starch, polyvinlypyrrolidone and magnesium stearate may be added to the co-micronizate of fenofibrate and solid surfactant (col. 1, line 67 – col. 2, line 4).

The preparation examples demonstrate distinct formulations of fenofibrate. For instance, Preparation I at column 2 demonstrates gelatin capsules containing fenofibrate (20.0 kg), sodium lauryl-sulfate (0.7 kg), alpha-lactose monohydrate (10.1 kg), pregelatinized starch (3.0 kg), crosslinked polyvinylpyrrolidone (0.7 kg) and magnesium stearate (0.5 kg). The fenofibrate/sodium lauryl-sulfate mixture is co-micronized in an air-jet micronizer to give a powder with a median particle size of 3 (μm). The lactose and the starch are then added to this powder and the whole is converted to granules in the presence of 8.9% of distilled water, relative to the total weight of the mixture. The granules obtained in this way are dried for one day at 50° C. and then graded so as to retain only the particles with sizes less than or equal to 1000 (μm). The polyvinylpyrrolidone and the magnesium stearate are then added and the whole is mixed until homogeneous. The powder obtained is used to fill size 1 gelatin capsules on an automatic machine with the compression set to a maximum of 150N.

Regarding the instantly claimed amounts and/or percentages, it is the position of the Examiner, that one of ordinary skill familiar with the art would be able to determine suitable amounts and/or percentages through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters.

Curtet teaches that the fenofibrate composition can be formulated into gelatin capsules. Curtet does not teach the composition in the form of a tablet. However, one of ordinary skill in the art would be capable of determining suitable forms of

administration (i.e., tablets, capsules, pills, powders) based on the desired or intended purpose. Such skill is also evident from the reference of Klimesch et al. (see below).

Klimesch *et al.* teach a continuous preparation and process for producing solid pharmaceutical forms comprising a mixture of one or more pharmaceutical active compounds, including fenofibrate with one or more pharmaceutically acceptable auxiliaries and polymers, such as polyvinylpyrrolidone, wherein the composition can be produced in the form of tablets or alternatively very small tablets which are advantageously filled into capsules, instead of conventional granules (see reference column 3, lines 1-18); (col. 3, line 67 – col. 4, line 56); (col. 5, line 10) and Abstract.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Klimesch with Curtet because Klimesch teaches pharmaceutical mixtures of active compounds and polymers that can be in the form of pharmaceutical tablets or alternatively, very small tablets that can be filled into capsules and similarly, Curtet teaches a mixture of an active compound (fenofibrate) with polymers (polyvinylpyrrolidone, surfactant) whereby the formulation can be produced into (gelatin) capsules. The expected result would be an improved micronized fenofibrate composition for effective treatment of hyperlipidemia and hypercholesterolemia, as similarly desired by the applicant(s).

Response to Arguments

Applicant's arguments with respect to claims 91-161 have been considered but are moot in view of the new ground(s) of rejection.

The applicants' arguments with respect to the Declaration under 37 C.F.R. §1.132 have been considered but were not found to be persuasive since the scope of the claims are not commensurate with the results compared in terms of the hydrophilic polymers and ratios. The prior art teaches the incorporation of hydrophilic polymers in a mixture with an active compound, fenofibrate. Hence, the instant invention remains unpatentable over the prior art.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
December 24, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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